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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/825,673	04/03/2001	Brady Esch	CARDE.57307	4482

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EXAMINER

SIRMONS, KEVIN C

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 09/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,673

Applicant(s)

ESCH ET AL.

Examiner

Kevin C. Simons

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-80 is/are pending in the application.
4a) Of the above claim(s) 38-43 and 48-72 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 73 is/are allowed.
- 6) ☐ Claim(s) 27,28,33-37,44-47 and 74-77 is/are rejected.
- 7) ☒ Claim(s) 29-32 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27, 28, 34, 37 and 44-47 are rejected under 35 U.S.C. 102(b) as being anticipated by Gallup et al U.S. Pat. No. 5,611,388.

Gallup discloses an aortic catheter comprising: an elongated shaft having a proximal end and a distal end (10), said elongated shaft of sufficient length to be inserted into an ascending aorta (10) and guided transluminally such that the distal end is positioned in a descending aorta when in an operative position (10); a flow control regulator positioned on said elongated shaft such that when said distal end is in the operative position said flow control regulator is capable of at least partially occluding the descending aorta (78); a proximal portion of said elongated shaft having a corporeal perfusion lumen (13) and an arch perfusion lumen (24, 76), (Note: applicant's currently amended functional language; (see fig. 1)) said arch perfusion lumen terminating as at least one (24 and (76, col. 7, lines 40-46) or more arch perfusion port proximate to a patient's arch vessels wherein said distal end is in the operative position; and a distal portion of said elongated shaft extending beyond said proximal portion, terminating as at least one or more corporeal perfusion port distal to said flow control regulator (fig. 1); as to claim 28, (col. 6, lines 11-14); as to claim 34, (78); as to claim 37, (86a and 86b); as to claim 44, (54); as to claim 45, (fig. 1); as to claim 46, (24, 76); as to claim 47, (13).

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 27, 28, 44-47 and 74-77 are rejected under 35 U.S.C. 102(e) as being anticipated by Bertolero et al U.S. Pat. No. 5,868,703.

Bertolero discloses an aortic catheter system comprising: corporeal perfusion port, flow regulator, arch perfusion port, and a cardiopulmonary bypass machine (figs. 1-11); as to claim 74, (see above rejection); as to claim 75, (col. 17, lines 25-38); as to claim 76, (figs. 1-11); as to claim 77, (col. 2, lines 46-67); and as to claims 28 and 44-47, (figs. 1-11).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 33, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gallup et al U.S. Pat. No. 5,611,388.

Gallup discloses an aortic catheter substantially as claimed. However, it may not be clear if he discloses an actuation source. Gallup discloses that his device can be inflated by a means well known in the art (col. 8, lines 1-4). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Gallup to use

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any actuation source for actuating a balloon/flow regulator, since Gallup clearly discloses that his device can be actuated by a means well known in the art.

As to claims 35 and 36, Gallup discloses an aortic catheter substantially as claimed except for the claimed dimension and material of the balloon. It would have been an obvious matter of design choice to modify Gallup to have the dimensions and material as specified by applicant, since applicant has not disclosed that having the catheter dimensions and material of the balloon solves any stated problem or is for any particular purpose and it appears that the catheter would perform equally well with any known aortic balloon catheter in the art.

Response to Arguments

Applicant's arguments filed 6/23/03 have been fully considered but they are not persuasive.

In response to applicant's argument that no suggestion is made that such structure is to be configured so as to support specific circulatory requirements as is now specifically called out for in claim 27 nor that the arch perfusion ports are to be positioned relative the distal end of the elongated shaft as now claimed, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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Applicant has not claimed a pump and it is the examiner's position that the connectors of Gallup are fully capable of performing the functions as set forth by applicant. Catheters are dimensioned to support bodily fluid including corporeal fluid.

As to the Bertolero reference, corporeal perfusion ports are positioned proximal and distal the flow control regulator as claimed in the underlying independent claim 27 (See figure. 4). Additionally, it is noted that the lumen 36 that terminates in port 37 distal to the balloon is not only limited to supply "biologically active fluids" but can also be used to evacuate fluid (i.e., vent the left ventricle, or carry a guidewire or various types of probes or for treating the heart (col. 11, lines 65-67). Therefore, since the lumen 36 and port 37 can provide the above functions, then it is certainly capable of corporeal perfusion without destroying the device.

Finally, with respect to independent claim 74, Bertolero clearly discloses a flow control regulator between ports capable of providing arch and corporeal support, and additionally provide for the supply of oxygenated blood through both ports. (see cardiopulmonary support machine in Bertolero)

Note: Applicant's claims have very little structure but have a plethora of functional language, which does not structurally differentiate the claimed device over the prior art of record. It is suggested that applicant add more structure or change the apparatus claims to a method claims to better place the case in condition for allowance. Basically, the prior art of record is capable of performing all of the added functional language to the claims.

Allowable Subject Matter

Claim 73 is allowable over the prior art of record.

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With respect to independent claim 73, the prior art of record discloses an aortic catheter system substantially as claimed except for CP machine coupled to the arch perfusion lumen and the corporeal lumen.

Claims 29-32 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

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KCS

Kevin C. Sirmons

Patent Examiner

9/5/03

Michael J. Hayes

MICHAEL J. HAYES
PRIMARY EXAMINER